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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/789,376

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Thomas H. Schulte

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 5400
SEATTLE, WA 98104

EXAMINER

DRODGE, JOSEPH W

ART UNIT

PAPER NUMBER

1723

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

12/29/2006

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/789,376

Applicant(s)

SCHULTE ET AL.

Examiner

Joseph W. Drodge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>07162004</u> . | 6) <input type="checkbox"/> Other: ____ |

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 11 and 27-31 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 20 and 15-19, respectively of prior U.S. Patent No. 6,742,661. This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

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F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,742,661.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic variations of the claims of '661, substantially only differing in omitting recitation of the microfluidic circuit having at least one port hole in communication with at least one well of the well plate. Otherwise the instant claims differ only in the arrangement of such limitations in different sequences of dependent claims pertaining to structure of an H-filter, microfluidic channels being in parallel, and one well having a bottom higher than another well.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 11-17, 22-26 and 32-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Pfost et al patent 6,485,690. Pfost et al disclose a well plate having an array of wells and microfluidic channel structures and networks connecting the wells (column 2, lines 35-64 and column 6, lines 1-46). The following are also disclosed: for claims 11, 15 and 38, structure containing a plurality of laminated or stacked well plates having wells in different layers (column 6, lines 22-25), hence above or below each other, for claims 12 and 16, arrays of the cited number of wells in well-plate formats (column 8, lines 59-65 and column 9, lines 5-30), for claims 13, 14 and 17 and also 32-38, microfluidic structures connecting numerous numbers of wells in parallel (figures 24a – 24c and corresponding column 12, line 37-column 13, line 64 and also see column 10, lines 40-47 and column 11, line 65-column 12, line 3), for claims 22, microfluidic cards or protective housings/coverings for groups of wells on a well plate (column 16, lines 18-51), for claim 23 hinge or similar connecting mechanisms (column 14, lines 17-23), for claim 24, pressure-application mechanisms (column 15, lines 30-31), for claim 25. diaphragm-type membrane applicators (column 14, line 21), for claim

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26, pressure application finger-like structures (column 14, lines 14-16 "barbed tab members) , for claims 33-35 the microfluidic channels optionally lying atop each other or being linear or curved (column 15, lines 19-21, column 18, lines 13-19), for claims 36-38 combining of fluid samples and combining of fluids, generally (column 13, lines 14-16 and other text).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-10, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pfoest et al patent 6,485,690 in view of Yager et al patent 5,932,100.

These claims differ from Pfoest et al in requiring at least one microfluidic structure in the form of an H-filter. However, Pfoest et al teach structures communicating the wells and other reservoirs in adjacent plates, and operable to react or separate interacting fluids within or between the plates (column 9, lines 40-48 and column 10, line 37-column 11, line 55). Yager et al '100 teach microfabricated H-filter structure (column 3, lines 33-50, column 5, lines 28-48 and column 8, lines 6-31) configured to communicate with upstream or downstream microstructures for analysis or sample obtaining (column 3, lines 18-31, see "integration"). It would have been obvious to one of ordinary skill in the art to have included one or a plurality of the H-Filters of the Yager et al '100 structure in the arrangement of Pfoest et al, in order to allow differential and/or laminar flow contact of fluid extraction streams with samples to be analyzed and to process picoliter to nanoliter size of sample arrays of samples utilizing low power consumption.

For claims 3-9 and 20, Yager et al '100 teaches at least two or possibly a larger plurality of both inlets and outlets, for claim 10, the inlets and outlets may be connected to diverse reservoirs or wells (column 10, lines 39-43). Plural inlets and outlets are also discussed in Pfoest at column 12, lines 26-37 and column 7, lines 14-30, etc.)

Claims 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pfoest et al patent 6,485,690 in view of one of Yager et al patent 5,716,852 or Dubrow et al patent 5,976,336.

These claims differ from Pfoest et al in requiring at least one microfluidic structure in the form of a T-sensor. However, Pfoest et al teach structures communicating the wells and other reservoirs in adjacent plates, and operable to react or separate interacting fluids within or between the plates. Yager et al '852 (column 5, lines 14-38) and Dubrow (column 3, lines 13-34) each teach microfabricated T-Sensor structures configured to communicate with upstream or downstream microstructures for analysis or sample obtaining. It would have been obvious to one of ordinary skill in the art to have included one or a plurality of the H-Filters of the Yager et al '100 structure in the arrangement of Pfoest et al, in order to allow laminar flow contact of fluid extraction streams with samples to be analyzed, and to facilitate analysis system designs incorporating lower material and/or space requirements.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached at 571-272-1151. The fax phone number for the examining group where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD

December 18, 2006

Joseph Drodge
Primary Examiner